The following corrections or additions to the January 1999 list were made in March 1999

New Approvals

ANADA Number: 200-247

Pioneer Product:	008-622
Trade Name:	Oxytetracycline HCl Soluble Powder-343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	02/10/99
Status:	Over-the-counter
Route:	Oral
Species:	Chickens, turkeys, cattle, swine, and sheep
Drug Form:	Powder
Concentration:	343 g/lb
Indications:	**Chickens:** For the control and treatment of infectious synovitis caused by *Mycoplasma synoviae*; chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*. **Turkeys:** For the control and treatment of hexamitiasis caused by *Hexamita meleagridis*; infectious synovitis caused by *Mycoplasma synoviae*; and control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis). **Cattle:** For the treatment and control in calves, beef cattle and nonlactating dairy cattle of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*. **Swine:** For the control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida*; and reducing the incidence of abortions and shedding of leptospira in breeding swine caused by *Leptospira pomona*. **Sheep:** For the treatment and control of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.
Tolerance:	21CFR 556.500: Tolerances are established for the sum of residues in tissues of cattle, beef calves, nonlactating dairy cattle, swine, chickens, turkeys, and sheep as follows: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	5 days

21CFR 520.1660d

ANADA Number: 200-241

Pioneer Product:	111-636
Trade Name:	Lincosol Soluble Powder
Ingredients:	Lincomycin hydrochloride
Sponsor:	Med-Pharmex, Inc.
Approval Date:	02/04/99
Status:	Over-the-counter
Route:	Oral
Species:	Swine, broiler chickens
Drug Form:	Powder
Concentration:	16 g / 40 g packet or scoop
Indications:	**Swine**: For the treatment of swine dysentery (bloody scours). **Broiler chickens**: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.
Tolerance:	21CFR 556.360: 0.6 ppm for parent lincomycin (marker residue) in the liver (target tissue) of swine and 0.1 ppm for parent lincomycin in muscle. The Acceptable Daily Intake (ADI) is established at 0.025 mg/kg of body weight/day.
Withdrawal:	6 days for swine, zero days for broiler chickens

21CFR 520.1263c

NADA Number: 141-110

Trade Name:	Coban®, Stafac®
Ingredients:	Monensin, virginiamycin
Sponsor:	Elanco Animal Health
Approval Date:	01/29/99
Status:	Over-the-counter
Route:	Oral
Species:	Growing turkeys
Drug Form:	Type A Medicated Articles to make Type C medicated feeds
Concentration:	Monensin 60 g/lb Type A Medicated Article; virginiamycin 20 and 277 g/lb Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency.
Withdrawal:	None

This application provides for the combined use of two approved Type A Medicated Articles in the manufacture of Type C medicated feeds.

21CFR 558.355

NADA Number: 141-060

Trade Name:	Deccox®-M Medicated Powder for Whole Milk
Ingredients:	Decoquinate
Sponsor:	Alpharma, Inc.
Approval Date:	01/14/99
Status:	Over-the-counter
Route:	Oral
Species:	Calves (ruminating and non-ruminating, including veal calves)
Drug Form:	Powder
Concentration:	0.8%
Indications:	For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in ruminating and non-ruminating calves, including veal calves.
Tolerance:	21CFR 556.170: 1ppm for skeletal muscle and 2 ppm for other tissues. The Acceptable Daily Intake (ADI) is 75 mcg/kg of body weight/day for total residues.
Withdrawal:	None

21CFR 520.534 and *556.170*

NADA Number: 141-097

Trade Name:	Ivomec® Premix for Swine + BMD®
Ingredients:	Ivermectin, bacitracin methylene disalicylate
Sponsor:	Merial Ltd.
Approval Date:	02/03/99
Status:	Over-the-counter
Route:	Oral
Species:	Swine (growing and finishing, and pregnant sows)
Drug Form:	Type A Medicated Articles to make Type B and C medicated feeds
Concentration:	Ivermectin - 0.6%, bacitracin methylene disalicylate - 30, 50, 60, and 75 g /lb
Indications	For the treatment and control of the following parasite: Gastrointestinal roundworms (*Ascaris suum* - adults and fourth-stage larvae; *Ascarops strongylina* - adults; *Hyostrongylus rubidus* - adults and fourth-stage larvae; *Oesophagostomum* spp. - adults and fourth-stage larvae) Kidney worms (*Stephanurus dentatus* - adults and fourth-stage larvae) Lungworms (*Metastrongylus* spp. - adults), Threadworms (*Strongyloides ransomi* - adults and somatic larvae and for the prevention of transmission of infective larvae to piglets, *via* the colostrum or milk, when fed during gestation), Lice (*Haematopinus suis*) Mange mites (*Sarcoptes scabiei* var. *suis*) For increased rate of weight gain and improved feed efficiency in growing and finishing swine, for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets, for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.
Tolerance:	21CFR 556.344 Ivermectin: An Acceptable Daily Intake (ADI) for total residues of ivermectin is 1 microgram/kg of body weight per day. A tolerance of 20 ppb in liver (the target tissue) and muscle has been established for residues of 22, 23-dihydroavermectin B_1a (the marker residue). 21CFR 556.70 Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of swine.
Withdrawal:	5 days

21CFR 558.300 and 558.76

Supplemental Approvals

ANADA Number: 200-144

Trade Name:	Oxytetracycline HCl Soluble Powder
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Merial, Ltd.
Approval Date:	12/16/98

This supplemental application provides for use of a larger (5 pound) package size.

21CFR 520.1660d

ANADA Number: 200-026

Trade Name:	Pennox 343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	PennField Oil Company
Approval Date:	02/05/99
Status:	Over-the-counter
Route:	Oral
Species:	Chickens, turkeys, cattle, swine, and sheep
Drug Form:	Powder
Concentration:	102.4 g / 4.78 oz packet or 512 g / 23.9 oz packet
Indications:	**Chickens:** For the control and treatment of infectious synovitis caused by *Mycoplasma synoviae*; chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*. **Turkeys:** For the control and treatment of hexamitiasis caused by *Hexamita meleagridis*; infectious synovitis caused by *Mycoplasma synoviae*; growing turkeys-complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis). **Cattle:** For the treatment and control in calves, beef cattle and nonlactating dairy cattle of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*. **Swine:** For the control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida*; and for breeding swine, leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona.* **Sheep:** For the treatment and control of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.
Tolerance:	21CFR 556.500: Tolerances are established for the sum of residues in tissues of cattle, beef calves, dairy calves, swine, chickens, and turkeys as follows: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal:	Revised withdrawal period for turkeys to zero days.

This supplemental application(s) provides for a zero days revised withdrawal period for turkeys and for use of an additional larger (23.9 oz) package size.

21CFR 520.1660d

NADA Number: 096-298

Trade Name:	Bovatec® Type A Medicated Article
Ingredients:	Lasalocid
Sponsor:	Roche Vitamins, Inc.
Approval Date:	02/05/99
Status:	Over-the-counter
Route:	Oral
Species:	Rabbits
Drug Form:	Type A Medicated Article to make Type C medicated feed
Concentration:	68 g /lb Type A Medicated Article
Indications:	For the prevention of coccidiosis in young rabbits caused by *Eimeria stiedae*.
Tolerance:	21CFR 556.347: 0.7 ppm for parent lasalocid in liver.
Withdrawal:	None

This supplemental application provides for the addition of a species and class (young rabbits) at a new lower concentration.

21CFR 558.311 and *556.347*

NADA Number: 065-470

Trade Name:	BMD® Soluble
Ingredients:	Bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	02/02/99
Status:	Over-the-counter
Route:	Oral
Species:	Replacement chickens
Drug Form:	Powder
Concentration:	51.2 g / 4.1 oz packet
Indications:	As an aid in the prevention and control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.
Tolerance:	21CFR 556.70: 0.5 ppm for residues of edible uncooked tissues
Withdrawal:	Zero days

This supplemental application provides for the addition of a new class, replacement chickens, to the previously approved product.

21CFR 520.154a

NADA Number: 034-025

Trade Name:	Lincocin® Sterile Solution; Lincomix® Injectable
Ingredients:	Lincomycin hydrochloride monohydrate
Sponsor:	Pharmacia and Upjohn Co.
Approval Date:	08/25/98
Status:	Over-the-counter
Route:	Intramuscular
Species:	Dogs, cats, and swine
Drug Form:	Liquid (solution)
Concentration:	25, 100, or 300 mg/mL
Indications:	**Dogs and cats**: Infections caused by Gram-positive organisms, particularly streptococci and staphylococci. **Swine**: Treatment of infectious arthritis and mycoplasma pneumonia.
Tolerance:	21CFR 556.360: 0.6 ppm for parent lincomycin (marker residue) in the liver (target tissue) of swine and 0.1 ppm for parent lincomycin in muscle. The Acceptable Daily Intake (ADI) is established at 0.025 mg/kg of body weight/day.
Withdrawal:	Swine: 2 days
Exclusivity:	3 years

This supplemental application provides for the new tolerances for lincomycin in swine and the establishment of an ADI for total residues of lincomycin.

21CFR 556.360

NADA Number: 097-505

Trade Name:	Lincomix® 10/20/50 Feed Medications
Ingredients:	Lincomycin hydrochloride monohydrate
Sponsor:	Pharmacia and Upjohn Co.
Approval Date:	08/25/98
Status:	Over-the-counter
Route:	Oral
Species:	Swine, broiler chickens
Drug Form:	Type A Medicated Articles and Type B medicated feed
Concentration:	Lincomix® 10 is a Type B medicated feed at 10 g/lb, Lincomix® 20 and 50 are Type A Medicated Articles at 20 and 50 g/lb respectively.
Indications:	**Broiler chickens**: For increased rate of weight gain and improved feed efficiency, and for the control of necrotic enteritis. **Swine**: For treatment and control of swine dysentery, for reduction of severity of mycoplasma pneumonia, and for increased rate of weight gain in growing-finishing swine.
Tolerance:	21CFR 556.360: 0.6 ppm for parent lincomycin (marker residue) in the liver (target tissue) of swine and 0.1 ppm for parent lincomycin in muscle. The Acceptable Daily Intake (ADI) is established at 0.025 mg/kg of body weight/day.
Withdrawal:	Zero days

This supplemental application provides for the new tolerances for lincomycin in swine, the establishment of an ADI for total residues of lincomycin, and a revised withdrawal time.

21CFR 520.1263c, 556.360, and 558.325

NADA Number: 111-636

Trade Name:	Lincomix® Soluble Powder
Ingredients:	Lincomycin hydrochloride monohydrate
Sponsor:	Pharmacia and Upjohn Co.
Approval Date:	08/25/98
Status:	Over-the-counter
Route:	Oral
Species:	Swine, broiler chickens
Drug Form:	Powder
Concentration:	32 g / 80 g packet
Indications:	**Broiler chickens**: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. **Swine**: For the treatment of swine dysentery (bloody scours).
Tolerance:	21CFR 556.360: 0.6 ppm for parent lincomycin (marker residue) in the liver (target tissue) of swine and 0.1 ppm for parent lincomycin in muscle. The Acceptable Daily Intake (ADI) is established at 0.025 mg/kg of body weight/day.
Withdrawal:	Zero days

This supplemental application provides for the new tolerances for lincomycin in swine, the establishment of an ADI for total residues of lincomycin, and a revised withdrawal time.

21CFR 520.1263c, 556.360, and 558.325

NADA Number: 141-061

Trade Name:	Dectomax® 1% Injectable Solution for Cattle and Swine
Ingredients:	Doramectin
Sponsor:	Pfizer, Inc.
Approval Date:	02/01/99
Status:	Over-the-counter
Route:	SQ or IM (cattle)
Species:	Beef cattle and non-lactating dairy cattle
Drug Form:	Solution
Concentration:	10 mg/mL
Indications:	For the treatment and control of the following in cattle. Gastrointestinal roundworms*: Ostertagia ostertagi* - adults and fourth-stage larvae; *Ostertagia ostertagi* - inhibited fourth-stage larvae; *Ostertagia lyrata* - adults and fourth-stage larvae; *Haemonchus placei* - adults and fourth-stage larvae; *Trichostrongylus axei* - adults and fourth-stage larvae; *Trichostrongylus colubriformis* - adults and fourth-stage larvae; *Trichostrongylus longispicularis* - adults; *Cooperia oncophora* - adults and fourth-stage larvae; *Cooperia punctata* - adults and fourth-stage larvae; *Cooperia pectinata* - adults; *Cooperia surnabada (syn. mcmasteri)* - adults and fourth-stage larvae; *Bunostomum phlebotomum* - adults; *Strongyloides papillosus* - adults; *Oesophagostomum radiatum* - adults and fourth-stage larvae; *Trichuris* spp. - adults Lungworms: *Dictyocaulus viviparus* - adults and fourth-stage larvae Eyeworms: *Thelazia* spp. - adults Grubs: *Hypoderma bovis, Hypoderma lineatum* Lice: *Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus* Mange mites: *Psoroptes bovis, Sarcoptes scabiei*
Tolerance:	21CFR 556.225: 0.1 ppm parent doramectin (the marker residue) in cattle liver (the target tissue) and 30 ppb in cattle muscle. The ADI is 0.75 mcg/kg of body weight/day for total residues.
Withdrawal:	35 days
Exclusivity:	3 years

This supplemental application provides for a new indication, which is additional persistent efficacy to protect cattle from reinfection with *Haemonchus placei* for 14 days after treatment.

21CFR 522.770

NADA Number: 141-070

Trade Name:	Rapinovet™
Ingredients:	Propofol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	01/14/99
Status:	Prescription only
Route:	Intravenous
Species:	Cats
Drug Form:	Liquid (emulsion)
Concentration:	10 mg/mL
Indications:	Anesthetic use in cats as follows: 1) As a single injection to provide general anesthesia for short procedures, 2) for induction and maintenance of general anesthesia using incremental doses to affect, and 3) for induction of general anesthesia where maintenance is provided by inhalant anesthetics.
Exclusivity:	3 years

This supplemental application provides for the addition of a new species, cats, to the original approved application.

21CFR 522.2005

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-064

Trade Name:	Pulmotil® 90 Type A Medicated Article
Ingredients:	Tilmicosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	02/02/99
Status:	Veterinary Feed Directive
Route:	Oral
Species:	Swine
Drug Form:	Type A Medicated Article to make Type B or C medicated feeds.
Concentration:	90.7 g/lb of Type A Medicated Article
Indications:	For the control of swine respiratory disease associated with *Actinobacillus pleuropneumonia* and *Pasteurella multocida.*
Tolerance:	21CFR 556.735: A tolerance is established for residues of parent tilmicosin (marker residue) in liver of swine (target tissue) at 7.5 ppm and 0.1 ppm parent tilmicosin in swine muscle. The acceptable daily intake (ADI) of 25 mcg/kg of body weight/day has been established.
Withdrawal:	7 days

This supplemental application provides for the addition of a CAUTION statement to the labeling, and provides tolerance information to establish an acceptable daily intake (ADI).

21CFR 556.735 and 558.618

Change of Sponsor Name

NADA Number: 200-237

From: Rhodia Limited
To: Rhodia Organique Fine Limited
Drug labler code: 059258

Change of Sponsor

NADA Number: 200-144

From: Rhone Merieux Canada, Inc.
To: Merial, Ltd.
Drug labeler code: 050604

Suitability Petition Action

Number:	**98P-1037/CP1**
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug trimethoprim/sulfadiazine which differs from the listed product, trimethoprim/sulfadiazine (Uniprim™ Powder), Macleod Pharmaceuticals, Inc., ANADA 200-033 by the following characteristics: Trimethoprim/sulfadiazine generic differs in dosage form from the listed product.
Action:	Approved on 03/03/99

Number:	**98P-1231/CP1**
Sponsor:	Superior Equine Pharmaceuticals, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, phenylbutazone, Anthony Products Co., NADA 049-187, by the following characteristics: Phenylbutazone generic is a powder dosage form where as the pioneer product is a tablet.
Action:	Approved on 03/03/99

Number:	**98P-1196/CP1**
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (Rapinovet™), Schering-Plough Animal Health Corp., NADA 141-070, by the following characteristics: Propofol generic differs in concentration and the addition of a preservative from the pioneer product.
Action:	Denied on 03/26/99

Number:	**99P-0627/CP1**
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug clorsulon which differs from the pioneer product, ivermectin/clorsulon (Ivomec® F Injection for Cattle), Merial Ltd., NADA 140-833, by the following characteristic: Clorsulon generic is a is a single ingredient product where as the pioneer product is a combination product.
Action:	Filed on 03/22/99